IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO: WAVE 4 CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF HOWARD JORDI, PH.D.

Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson (collectively, "Defendants"), submit this memorandum in support of their motion to exclude the opinions and testimony of Howard Jordi, Ph.D.

Introduction

Ethicon moves this Court for an order excluding or, alternatively, limiting the testimony of Howard Jordi, Ph.D. Dr. Jordi offers several opinions concerning *in vivo* degradation of the surface layer of the Prolene mesh fibers used in various Ethicon products. However, he has admitted that not all degradation is clinically significant. There is no reliable evidence or opinion establishing that degradation *in vivo* is clinically significant, either in general or with respect to these Plaintiffs' specific mesh implants. Without evidence of clinical significance, Dr. Jordi's opinions are unhelpful and should be excluded in their entirety. The cases to which this motion applies are identified in Ex. A to this motion.

Alternatively, if Dr. Jordi is allowed to testify, the Court should limit his opinions. This Court has previously held that Dr. Jordi could not rely on his chemical analysis of third-party

mesh explants in support of his testimony that Prolene mesh degrades *in vivo*.[1] To the extent that Dr. Jordi attempts to offer opinions in this case based on his analysis of those mesh explants, his testimony should be excluded.

Dr. Jordi also offers opinions in this case based on documents produced by Ethicon concerning certain testing and analysis conducted on Prolene sutures some thirty years ago that appeared to show degradation that was not clinically significant. This testimony is preempted by federal law. In the alternative, if Dr. Jordi attempts to offer opinions on the alleged *in vivo* degradation of Prolene polypropylene sutures based upon those or other documents, Ethicon should be permitted to offer evidence that the FDA specifically approved and has regulated the use and labeling of Prolene polypropylene for these sutures since it approved the New Drug Application for Prolene polypropylene sutures in 1969.

Dr. Jordi should also be precluded from talking about the brittleness and other mechanical properties of degraded polypropylene. Dr. Jordi has repeatedly stated that his opinions regarding degradation of Prolene are limited to the surface layer of the mesh fibers, which he has measured as being only 1-micron deep. That layer—which Ethicon believes is, in fact, protein remaining from the explant—sits on the outside of a much larger filament. Dr. Jordi has not opined and cannot opine that the mechanical properties of this 1-micron surface layer harm the patient, rendering the Prolene mesh defective for its intended use. Therefore, any opinions about the brittleness or other mechanical properties of the surface are unhelpful, irrelevant, and unduly prejudicial.

[1] *See* Ex. B, 2/12/14 Trial Tr., *Lewis v. Ethicon*, No. 2:12-cv-04301 (S.D. W. Va.), at 15:18–18:24 (precluding Dr. Jordi from testifying about his testing of non-party mesh explants because there was no evidence that these explants were representative of TVT or Prolene meshes in general).

Finally, Dr. Jordi's opinions about environmental stress cracking ("ESC") are unreliable. None of the articles or studies Dr. Jordi cites support his claims that Prolene polypropylene is susceptible to ESC. These opinions are inadmissible *ipse dixit*.

Summary of Opinions

Dr. Howard Jordi, Ph.D. is a polymer scientist. *See* Ex. C, Jordi Report at 2. Dr. Jordi has adopted his Wave 1 report for Wave 4. Based on his knowledge, training, experience, review of scientific literature, review and analysis of Ethicon Prolene polypropylene mesh explants from this litigation, and review of internal Ethicon documents, Dr. Jordi opines that:

(1) "Polypropylene can and does undergo in vivo degradation";

(2) The Prolene polypropylene used to make Prolene mesh "can and does undergo *in vivo* degradation";

(3) "The antioxidants used to protect Ethicon's Prolene pelvic floor and stress urinary incontinence devices from oxidation leach out of the mesh fibers into the surrounding tissue leaving the TVT [*sic*] devices highly susceptible to in vivo degradation";

(4) This degradation of Prolene polypropylene mesh causes the mesh devices "to become brittle," as "demonstrated by significant cracking observed in the peer-review publications and Ethicon's internal documents and which is consistent with [his] own experience in observing these devices under" scanning electron microscopy ("SEM");

(5) Prolene polypropylene "is susceptible to environmental stress cracking" ("ESC") due to the process used to manufacture it; and

(6) the absorption of cholesterols and fatty acids "into Ethicon's Prolene pelvic floor and stress urinary incontinence devices . . . make[s] the devices susceptible to environmental stress cracking which likely contributed to the degradation and cracking *in vivo* as observed in the SEM images" of the mesh explants.

(*Id.* at 24–25.) Dr. Jordi's opinions and report are discussed in more detail below.

Argument

I. Dr. Jordi's opinions are unhelpful and speculative because there is no reliable evidence showing when the alleged degradation becomes clinically significant, if ever.

Although Dr. Jordi cites numerous studies for his theory that Prolene degrades *in vivo*, he does not cite a single study showing that this degradation is clinically significant. There is no reliable evidence or opinion in the record establishing that Prolene degradation is or can be clinically significant. Because Plaintiffs cannot establish clinical significance of degradation, Dr. Jordi's opinions are unhelpful and speculative.

Even assuming that Prolene degrades, this degradation can only be relevant if the Plaintiffs can link degradation to some sort of complication. Therefore, without a reliable foundation showing that Prolene degradation is clinically significant, any opinions on degradation are unhelpful.

Dr. Jordi has admitted that not all degradation is clinically significant. In a recent trial in Texas, Dr. Jordi testified that not all Prolene degradation was clinically significant:

> Q. And is there a difference between sig—significant or clinical sig—or degradation that would have clinical significance and degradation that would have no clinical significance? You can have degradation that would have no clinical significance, can't you?
>
> **A. You know, yes, that should be possible.**

Ex. D, *Batiste v. Johnson & Johnson*, No. DC-12-14350, Trial Tr., Vol. 8, at 151:9–14 (Tex. 95th Jud. Dist. Ct. Mar. 21, 2014). Similar to this case, the degradation at issue in *Batiste* was limited to a one-micron-thick surface layer that could not be seen with the naked eye. *Id.* at 112:17–114:9.

In the *Batiste* case, the Texas Court of Appeals overturned a jury verdict in the plaintiff's favor, finding that the plaintiff "failed to offer legally sufficient evidence that any alleged defect in the TVT-O was the producing cause of her injuries." *Johnson & Johnson v. Batiste*, No. 05-14-864-CV, 2015 WL 6751063 at *1 (Tex. App. 2015) (mem.). With respect to the argument that degradation caused the plaintiff's injuries, the *Batiste* Court found that Dr. Jordi's testimony on this issue was legally insufficient to establish causation:

> There was evidence that degradation of the polypropylene could enhance the opportunity for infection and increase inflammation. Jordi admitted, however, there could be degradation from the polypropylene that would have no clinical significance in a patient, and there was no evidence as to how much the polypropylene would have to degrade before it caused injury to a patient.

Id. at *6.

The Plaintiffs' cases suffer from a similar lack of evidence reliably showing a potential link between Prolene degradation and their alleged injuries. Dr. Jordi has admitted that not all degradation is clinically significant, and no Plaintiffs' expert has offered a reliable basis for determining the point at which degradation becomes clinically significant. Any opinion that a particular plaintiff's mesh degraded in a clinically significant manner would be speculative, at best. Without a reliable basis for establishing the clinical significance of degradation, both in general and as to specific plaintiffs, Dr. Jordi's degradation opinions are unhelpful and should be excluded.

The absence of a reliable basis for establishing that mesh degradation was clinically significant for the plaintiffs is, alone, a sufficient basis for excluding all of Dr. Jordi's opinions. All of his opinions concern various aspects of alleged degradation, and without clinical significance none of them have any relevance to these cases. For that reason, the Court need not reach the additional objections to his testimony which are detailed below for consideration if the Court decides to allow testimony about clinically insignificant degradation.

A. If reached, this Court has already held that Dr. Jordi cannot testify about his personal testing of non-party meshes produced in litigation because this testing is unreliable and unhelpful.

Dr. Jordi relies upon prior testing of explanted Prolene meshes he has performed in connection with pelvic mesh litigation cases to support his opinions in this case. *See* Ex. C, Jordi Report at 12–13, 15–23. The Court has previously ruled that testimony about testing non-party explants produced in other litigation is inadmissible.[2] Plaintiffs have not shown that any of the testing upon which Dr. Jordi relies overcomes the flaws found in the Court's prior rulings.

Dr. Jordi's general report for the Wave 1 cases does not show any testing of any mesh explants from any of the Wave 1 plaintiffs. This Court has previously ruled that Dr. Jordi cannot testify about testing he performed on non-party explants produced in litigation. In the *Lewis* trial, the Court precluded Dr. Jordi from testifying about explants other than the plaintiff's because there was no evidence that the other explants could be considered representative of the plaintiff's mesh.[3] In this case, plaintiffs' counsel still has not presented any evidence establishing that these

[2] *See* footnote 1, *supra*.

[3] *See* footnote 1, *supra*. Similarly, the Court, in *Lewis*, precluded Dr. Uwe Klinge, another one of the plaintiffs' experts, from testifying about mesh explants other than the plaintiff's. *See Lewis v. Ethicon* (*In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*), No. 2:12-cv-04301, 2014 WL 186872 at *8 (S.D. W. Va. Jan. 15, 2014). The Court found that Dr. Klinge's opinions regarding these explants were unreliable because there was no evidence of how these explants were selected. *Id.* Before Dr. Jordi testified in *Lewis*, plaintiffs' counsel presented such evidence but the Court still excluded Dr. Jordi's

non-party explants produced in litigation are representative of Prolene in general or of the plaintiffs' specific implants.

In his report for *Bellew v. Ethicon*, No. 2:13-cv-22473 (S.D. W. Va.), Dr. Jordi stated that the explants he tested were "selected randomly at Steelgate, the facility which was storing the explants after they were surgically removed by the patients' physicians." *See* Ex. E, *Bellew* Jordi Report at 85. The Court had already found that these samples from Steelgate are not representative of mesh implants in general. *See* Ex. B, 2/12/14 Trial Tr., *Lewis*, 17:8–17, 18:19–24. Thus, it is not surprising that, when the Defendants moved to preclude Dr. Jordi from testifying about these explants in *Bellew*, Dr. Jordi withdrew his opinions about these explants. *See* Mem. Op. & Order [ECF No. 265], *Bellew v. Ethicon*, No. 2:13-cv-22473 (S.D. W. Va.) at 10.

No good reason exists to depart from the Court's prior rulings with respect to these implants. Accordingly, the Court should preclude Dr. Jordi from testifying about his personal testing of non-party explanted Prolene meshes produced in other litigation and from relying upon this testing for his opinions.

B. The Court should preclude Dr. Jordi from relying on inapposite medical literature and on internal Ethicon studies.

In addition to relying on his unreliable testing of non-party explants, Dr. Jordi bases his degradation opinions on a handful of medical literature and internal Ethicon studies. However, none of the papers or internal Ethicon tests to which Dr. Jordi cites actually stands for the proposition that the Prolene in Ethicon mesh products oxidizes and degrades *in vivo*.

- **Not Prolene and Speculative**. Costello's *Materials Characterization of Explanted*

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opinions regarding these non-party explants due to lack of evidence that the explants were representative. *See* Ex. B, 2/12/14 Trial Tr., *Lewis*, at 15:18–18:24.

Hernia Meshes, 83B J. Biomed. Mater. Res Part B: Appl Biomater 44 (2007) analyzed only mesh manufactured by C.R. Bard, and not the Prolene at issue in this litigation. *See* Ex. F. Further, Costello's *Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants From a Single Patient*, 14 Surg. Innov. 168 (2007), did involve a Prolene Soft mesh, but did not test for degradation. Further, neither study reported the molecular weight of either pristine or explanted material. These studies are, therefore, inapposite.

- **Cannot Confirm Oxidation of Prolene or Polypropylene.** The Clave study, encompassing 100 meshes from multiple manufacturers, expressly states that while there are many "hypotheses concerning the degradation of the PP . . . [n]one of these, particularly direct oxidation, could be confirmed in this study." Ex. G, A. Clave, *et al.*, *Polypropylene As A Reinforcement In Pelvic Surgery Is Not Inert: Comparative Analysis of 100 Explants*, 21 Int. Urogynecol. J. 261, 266 (2010).

- **Not Prolene and Not Pelvic Mesh**. Nothing in the Wood study suggests that it analyzed Prolene. *See* Ex. H, A.J. Wood, *et al.*, *Materials Characterization and Histological Analysis of Explanted Polypropylene, PTFE, and PET Hernia Meshes from an Individual Patient*, 24 J. Mater. Sci. Mater. Med. 1113 (2013). Furthermore, the study expressly states that it analyzed hernia meshes, not meshes used in the pelvic floor. *See id.*

- **Not Prolene and Antioxidants work.** The Liebert study assessed filaments prepared from polypropylene manufactured by the Hercules Company, not the Prolene at issue in this litigation. Ex. I, T. Liebert, *et al.*, *Subcutaneous Implants of PP Filaments*, 10 J. Biomed. Mater. Res. 939, 941 (1976). In addition, as even Plaintiffs' experts have admitted, the Liebert study actually found that antioxidants are effective at preventing degradation in polypropylene. *See, e.g.*, Ex. J, Guelcher 3/25/14 Dep. 73:16–74:1.

- **Not Prolene and Speculative**. There is nothing in the Williams article that suggests that it dealt with Prolene. Ex. K, D.F. Williams, 17 *Biodegradation of Surgical Polymers*, J. of Mater. Sci. 1233 (1982). In addition, Williams expressly stated that "[a]ctivation energies for the degradation of high-molecular weight polymers used in surgery vary . . . [and] generally require either heat, u.v. light, or high energy radiation . . . to proceed. It seems certain from these conditions that no such degradation should occur within the confines of the human body." *Id.* at 1236. Williams also noted that while some authors have suggested that "enzymes may be influential in degrading polymers," it was "always without proof." *Id.* at 1237.

- **Not Prolene and Exposure to Conditions Not Found in the Pelvic Floor.** The paper by Sternschuss and Ostergard—a paid expert for plaintiffs in pelvic mesh litigation—is merely a literature review in which the authors assert that polypropylene degrades based solely on papers that do not support the proposition that Prolene implanted in the pelvic floor degrades. *See* Ex. L, G. Sternschuss, Donald Ostergard, *et al.*, *Post-Implantation Alterations of Polypropylene in the Human*, 188 J. of Urology 27, 30-31 (2012). For

> instance, as discussed above, the Costello, Clave, and Williams papers simply did not address Prolene. *See supra*.
>
> And while the Jongebloed paper may address Prolene, it is nonetheless inapposite because it examined only sutures that had been implanted in the human eye. Ex. M, W. Jongebloed, *et al.*, *Mechanical and Biochemical Effects of Man-Made Fibers and Metals in the Human Eye, A SEM Study*, 61 Documenta Opthamologica 303 (1986). It is undisputed that all forms of polypropylene, including Prolene, oxidize when exposed to ultraviolet radiation. Thus, the fact that ocular sutures—which would necessarily be exposed to ultraviolet radiation—oxidize after implantation in the eye is neither surprising nor germane to the Prolene used in Ethicon mesh products placed in the pelvic floor.

Dr. Jordi also seeks to support his opinion that Prolene degrades *in vivo* by referring to certain unpublished Ethicon documents regarding Prolene sutures and deposition testimony regarding these documents. Ex. C, Jordi Report at 14–24 & nn. 53–65. But these internal documents do not support Dr. Jordi's degradation opinions.

Dr. Jordi points to Ethicon's 1987 Prolene suture test as evidence that Prolene is subject to oxidative degradation. *See id.*; *see also* Ex. N, IR Microscopy of Explanted Prolene (Sept. 30, 1987), ETH.MESH.12831391–1404. But the 1987 suture test does not support Dr. Jordi's opinion that Prolene degrades *in vivo*, because it did not report a change in molecular weight in the sutures, which other experts for Plaintiffs in this litigation have acknowledged is a fundamental component of oxidative degradation. *See* Ex. O, Jordi 10/30/13 Dep. 173:25–174:8. Nor did the test make any findings that the sutures' mechanical properties—such as elongation and tensile strength—diminished.

Dr. Jordi cites numerous documents pertaining to Ethicon's "dog studies" as proof that Prolene oxidizes and degrades *in vivo*, but all of those documents are part of Ethicon's seven-year dog study of Prolene sutures. *See* Ex. C, Jordi Report at 14–24. Moreover, Dr. Jordi's reliance on the dog study is misplaced because—as Plaintiffs' experts concede—it reported no

significant loss of molecular weight. *See, e.g.*, Ex. P, Mays 3/2/16 Dep. 151:4-14 (admitting the study reported no significant loss of molecular weight and no "molecular weight degradation"). The study also indicates that the sutures were plasticized *in vivo*, which Plaintiffs' other materials scientists concede would actually improve the toughness of the suture. *Id.* at 154:2-13.

Ultimately, none of the studies or internal Ethicon documents supports Dr. Jordi's opinion that the Prolene used in Ethicon Mesh Products degrades in the human body. Accordingly, the Court should exclude his opinions based on these studies and internal documents as unreliable.

C. In addition, Dr. Jordi's opinions regarding Prolene polypropylene sutures should be excluded.

Many of Dr. Jordi's opinions are based on company studies and documents discussing sutures made from Prolene polypropylene. *See, e.g.*, Ex. C Jordi Report at 6–9 (discussing 1986 and 1998 studies on Prolene sutures) & 14–15 (discussing Ethicon dog study on sutures). However, none of these studies assign any clinical significance to the degradation observed and none conclude that degradation renders Prolene unsafe or ineffective for use as a suture.

Nevertheless, Dr. Jordi extrapolates from these studies that the Prolene polypropylene mesh in Ethicon's pelvic organ prolapse and stress urinary devices can degrade *in vivo*. Ethicon submits that Dr. Jordi should not be permitted to offer any testimony that Prolene polypropylene mesh degrades based on his review of Prolene polypropylene sutures, a medical device specifically approved and regulated by the FDA pursuant to the New Drug Application ("NDA") process.

If such testimony is permitted, then Ethicon should be permitted to introduce the FDA approval and regulatory process of the Prolene polypropylene sutures.

As the Court is aware, the FDA approved Prolene polypropylene sutures as an implantable medical device when it approved the Prolene polypropylene suture NDA in 1969. *See, e.g.*, Mem. Supp. Mot. Partial Summ. Judg. Based on Preemption [ECF No. 129], *Lewis v. Johnson & Johnson*, No. 2:12-cv-04301 (S.D. W. Va. Dec. 12, 2013), at 2–4. From 1976 to 1990, the FDA regulated Prolene sutures as a Class III medical device subject to the Premarket Approval (PMA) process. *See id.* at 4. In 1988, the FDA approved a label which says Prolene "is not subject to degradation or weakening by the action of the tissue enzymes." *Id.* In 1990, the FDA reclassified Prolene and other polypropylene sutures as a Class II device, subject to less rigorous controls, based on the proven safety and effectiveness of polypropylene sutures. *See id.* at 4–5. When it did so, the FDA recognized that studies have found that some polypropylene sutures degrade *in vivo*, but that this degradation "is generally not considered clinically significant under most circumstances of use." *See* Ex. Q, FDA Reclassification Letter at p. 9 [ETH.MESH.10665546].

As the Court has recognized, the FDA's Premarket Approval review is much more rigorous than the 510(k) process, and design defect claims for PMA-approved devices are typically preempted. *See, e.g.*, *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 751–52 (S.D. W. Va. 2014) (discussing differences between PMA and 510(k) processes and acknowledging that "tort claims regarding medical devices approved through the premarket approval process generally are preempted"). Thus, if the Plaintiffs were suing for alleged design defects in Prolene polypropylene sutures, their claims would be preempted in light of the FDA's approval of these devices.

Instead, Dr. Jordi is offering this same opinion in the context of Prolene polypropylene mesh products cleared through the 510(k) process. While this court has held such claims are not

preempted, Dr. Jordi's opinions clearly implicate the same policy concerns underlying preemption for FDA-approved devices. In essence, Dr. Jordi's reliance on studies or testing regarding degradation of polypropylene sutures is second-guessing the FDA's determination that the benefits of these sutures outweighed the risks. *See, e.g.*, *Walker v. Medtronic, Inc.*, 670 F.3d 569, 572 (4th Cir. 2012) (noting that, in enacting preemption provisions of Medical Devices Amendment, Congress "determined that the benefit to the many of bringing potentially lifesaving, but risky, medical devices to the public following the rigorous process of FDA approval outweighed the cost to the few of preempting common law claims based on different standards"). Therefore, if Dr. Jordi's testimony about Prolene sutures is allowed, Ethicon should be permitted to cross-examine Dr. Jordi with the FDA approval and the statements made by the FDA when it reclassified sutures in 1990.

For these reasons, the Court should preclude Dr. Jordi from testifying about or relying upon alleged degradation of sutures made from Prolene polypropylene.

D. The Court should preclude Dr. Jordi from testifying about brittleness or other mechanical properties of degraded Prolene.

One of Dr. Jordi's primary opinions is that *in vivo* degradation of Prolene causes Prolene mesh to become brittle. *See* Ex. C, Jordi Report at 24. Dr. Jordi has no reliable basis for this opinion, and the Court should preclude him from testifying about brittleness or other mechanical properties of Prolene polypropylene meshes. Further, even if reliable, any opinions about the mechanical properties of degraded Prolene are irrelevant, because Dr. Jordi has admitted that he measured only a one-micron-thick layer of Prolene that he claims degrades *in vivo*, and there is no evidence that the mechanical properties of this one micron thick surface layer—which Ethicon believes is protein clinging to the Prolene—are clinically significant.

1. Dr. Jordi's opinions about Prolene mesh's mechanical properties are not supported by any reliable methodology.

Dr. Jordi bases his brittleness opinion on the "significant cracking observed in the peer-review publications and Ethicon's internal documents." *Id.* at 25. However, he doesn't cite to or discuss any specific study showing that degradation of Prolene caused the sutures or mesh to become brittle or otherwise had a negative impact on the mechanical properties of the sutures or mesh.

Dr. Jordi does not provide a basis for concluding that surface cracking demonstrates brittleness or some other negative change in the mesh's mechanical properties.

Dr. Jordi has not performed any mechanical testing of allegedly degraded Prolene. Therefore, his testimony is inadmissible unless he can point to testing by others that supports his opinion. *See Oglesby v. General Motors Corp.*, 190 F.3d 244, 249 (4th Cir. 1999); *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). One of the studies Dr. Jordi relies on—Ethicon's 7-year dog study—found that, despite observations of surface cracking, the mechanical properties of the Prolene sutures actually *improved* over time. *See* Ex. R, 7-Year Dog Study, ETH.MESH.07690752-0756; *see* Ex. S, 2/14/17 MacLean Report at 57–64 (explaining mechanical testing results from 7-year dog study).

Dr. Jordi's other basis for his brittleness opinions is his personal examination of non-party explants produced in other litigation. As noted above, Dr. Jordi should be precluded from testifying about or relying upon these non-party explants produced in other litigation, because that sample is not reliably representative of Prolene polypropylene in general.

Further, Dr. Jordi's examination of that sample was far from reliable or scientific; he simply felt the mesh and thought it was brittle. Dr. Jordi did not conduct any objective tests of the mechanical properties of the explants, nor did he try to quantify the brittleness or other

mechanical properties of the explants. He did not compare the explants to a pristine control or to an alternative polymer that had also been implanted *in vivo*. He does not cite to peer-reviewed literature regarding the mechanical properties of degraded polypropylene or Prolene. Without any reliable, objective basis for his belief that degraded Prolene has different mechanical properties, Dr. Jordi's opinions on this topic should be excluded.

2. Any opinions about the mechanical properties of degraded Prolene are unhelpful, irrelevant, and unduly prejudicial, because Dr. Jordi has admitted his degradation opinions are limited to the surface layer of the Prolene fibers.

Dr. Jordi has repeatedly emphasized that his opinions about Prolene degradation are limited to the one-micron surface of the mesh fibers. There is no evidence that the mechanical properties of the surface layer are of any clinical or practical significance. As such, any opinions about the mechanical impact of degradation are irrelevant and unhelpful.

In his prior testing, Dr. Jordi measured the depth of one of the surface cracks he observed and found it to be 1 micron in depth:

> Q. . . . [T]he only test that you conducted to determine the thickness of the suture layer of what you identified to be degradation was approximately 1 micron, correct?
>
> . . .
>
> **A. We saw one – we measured one 1-micron crack. That's all I can tell you.**

See Ex. T, Jordi 8/19/14 Dep. Tr. 26:11–14; *see also* Ex. C., Jordi Report at 16–17; *id.* at 15 (noting that in his personal testing, he measured the surface cracking as approximately 1 micron).

Jordi repeatedly stated that his observations and opinions about the *in vivo* degradation of Prolene were limited to the cracked "surface" of the mesh fibers. *See* Ex. T, Jordi 8/19/14 Dep.

Tr. 87:20–23; 170:21–171:1 (testifying that degradation was "limited to the surface of the explant" and was a "surface phenomenon").

Dr. Jordi's current expert report notes, in multiple places, that the alleged degradation of Prolene polypropylene was only observed on the surface layer. *See* Ex. C, Jordi Report at 7–8, 11, 14–15, 22. Indeed, Dr. Iakovlev, Plaintiffs' expert pathologist, has offered the opinion that the alleged degradation of the surface of the Prolene mesh stops and does not appear past this outside layers. *See* Ex. U, Iakovlev 9/11/15 Dep. Tr. 94:15-95:5.

There is no evidence that the mechanical properties of this allegedly degraded 1-micron surface layer somehow render Prolene mesh unsafe for its intended use in these cases. There is also no evidence that a Prolene mesh used in a pelvic organ prolapse or stress urinary incontinence device is rendered unsafe or ineffective by the presence of a 1-micron-thick allegedly degraded surface layer. Thus, there is no evidence that a change in the mechanical properties of the surface layer of Prolene mesh constitutes a potential design defect.

To allow Dr. Jordi to testify about brittleness or any other mechanical properties of degraded Prolene is therefore unhelpful, irrelevant, and unduly prejudicial. There is no evidence that a change in the mechanical properties of the surface layer of the mesh would affect the safety or efficacy of a Prolene mesh device as a whole. Accordingly, the Court should preclude Dr. Jordi from testifying about brittleness or other mechanical impacts of degradation.

II. Dr. Jordi's opinions about environmental stress cracking are unreliable.

Dr. Jordi opines that, due to the manufacturing process and absorption of cholesterols and fatty acids, Prolene polypropylene is susceptible to environmental stress cracking ("ESC"), a form of degradation caused by mechanical stress. *See* Ex. C, Jordi Report at 5, 24. However, his report does not provide any reliable basis for these opinions.

Dr. Jordi does not cite any study for the proposition that Prolene is subject to ESC. The studies that Dr. Jordi cites attribute surface cracking to possible oxidation rather than ESC. *See, e.g.*, *id.* at 6 (citing studies that show polypropylene can degrade due to lack of antioxidants); *id.* at 11 (citing Wood study's conclusion that surface cracking was the result of oxidative degradation). Further, Dr. Jordi does not identify in his Report how the manufacturing process contributes to or causes ESC; he doesn't even describe this manufacturing process. Similarly, Dr. Jordi does not identify any peer-reviewed studies or internal Ethicon studies finding absorption of cholesterols and fatty acids in Prolene polypropylene or linking this absorption to an increased risk of ESC.[4]

Dr. Jordi's opinions appear to be based solely on his personal testing of non-party explants produced in litigation. In other cases, Dr. Jordi based his ESC opinions on his testing of the other plaintiffs' explants. *See* Ex. O, Jordi 10/30/13 Dep. Tr. 89:3–90:22 (testifying in *Batiste* that visual observations, change of melting point, and presence of cholesterols in explant were evidence of ESC); *see* Ex. T, Jordi 8/19/14 Dep. Tr. 85:2–21 (same for *Bellew*). As noted above, Dr. Jordi may not rely upon his personal testing of other plaintiffs' explants produced in litigation, because these explants are not reliably representative of Prolene meshes in general.

With respect to the explants at issue in this case, Dr. Jordi's ESC opinions are nothing but *ipse dixit*. He does not cite any reliable methodology linking the alleged one micron surface cracking with ESC. He does not cite to any reliable evidence, methodology, or research that

[4] The only mention of cholesterols and fatty acids in Dr. Jordi's Report is his description of a 2010 Clave study. *See* Ex. C, Jordi Rep. at 6; *see also* Ex. G, Clave, et al., "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants," Int. Urogyn. J. & Pelvic Floor Dysfunction (2010) 21:261-270 ["Clave"]. This article never mentions ESC or mechanical degradation and does not link fatty acid or cholesterol absorption to ESC. *See generally* Ex. G, Clave. Further, this article notes that some samples of polypropylene showed no signs of degradation, despite also showing evidence of absorption of cholesterol and fatty acids. *Id.* at 267. Thus, the Clave study does not support Dr. Jordi's opinion that Prolene polypropylene is susceptible to ESC.

suggests that any of the Plaintiffs' meshes in this case has undergone or will undergo ESC, either due to the manufacturing process or absorption of fatty acids and cholesterol. As such, the Court should preclude Dr. Jordi from offering any opinions at trial concerning ESC. *See, e.g.*, *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 701 (S.D. W. Va. 2014) (Improper testing insufficient: "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)) (alteration in original)).

III. Conclusion

For the reasons stated above, the Court should exclude Dr. Jordi's testimony from trial because he cannot show that the alleged degradation is clinically significant. Alternatively, the Court should limit Dr. Jordi's testimony at trial by precluding him from: (1) testifying about or relying upon his testing of non-party explants, (2) testifying about or relying upon medical literature or internal Ethicon documents, (3) testifying about Prolene polypropylene sutures (unless the Defendants are allowed to introduce evidence of the FDA's approval of these sutures), (4) testifying about the brittleness or other mechanical properties of degraded polypropylene or Prolene, and (5) testifying about or opining that Prolene mesh is susceptible to ESC.

Respectfully submitted,

ETHICON, INC., ETHICON LLC, AND JOHNSON & JOHNSON

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 4 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I certify that on April 13, 2017, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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